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PATENT SPECIFICATION

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COMPLETE SPECIFICATION

Hypodermic Ampoules

I, HANNAH DUNMIRE, a Citizen of United States of America, of 29550 Pike Drive, Chagrin Falls, Ohio, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates generally to hypodermic injection devices, and more specifically to improvements in disposable hypodermic ampoules.

The basic construction of such a hypodermic ampoule or syringe may comprise a body having the general form of an inverted, cup-shaped shell and a disk-like diaphragm peripherally sealed to the body across its mouth to define a collapsible reservoir for containing a prescribed volume of hypodermic liquid. Contained entirely within the sealed ampoule body is a hypodermic needle having a cannula with a pointed discharge end, the needle cannula being disposed in axial alignment with the body and with the pointed end extending toward, but terminating short of the lower end wall or diaphragm. The butt end of the needle is secured adjacent the inner, upper end wall surface of the inverted, cup-shaped shell, and an opening into the butt end of the needle is exposed to the hypodermic liquid so that the liquid can flow freely into and through the needle during the administration of an injection.

In use, the ampoule is positioned with the diaphragm against the skin and pressure is applied to the top of the ampoule to collapse it axially inwardly. When collapsing pressure is initially applied, the pointed end of the hypodermic needle is forced downwardly to pierce the diaphragm. Further pressure results in the needle being inserted through the skin and the ampoule body being collapsed to discharge the hypodermic liquid through the needle into or under the skin.

In order to assure a safe, reliable, and practical manner of administering a hypodermic injection, devices of the type described must satisfy two basic requirements. The first of these requirements is that the ampoule be capable of discharging in excess of 90% of the contained hypodermic liquid. The primary reason for this requirement is, of course, to assure that an accurate dosage can be administered with each ampoule. A maximum discharge from the ampoule also is important from the standpoint of preventing waste of the hypodermic liquid.

The second basic requirement of hypodermic ampoules is that the minimum evacuation of 90% can be obtained by a manually applied force of not more than 10 or 12 pounds. If a greater force is required to collapse the ampoule and effect the injection, the danger exists that the user will discontinue the injection before the full dosage has been administered.

While the hypodermic ampoules proposed hitherto have been successfully used in many applications, there has been found a need for certain improvements in their construction in order to completely satisfy the aforementioned requirements and overcome certain problems.

One of these problems has been the possible occurrence of a "hydraulic lock" making it virtually impossible to initially collapse the ampoule body to force the hypodermic needle through the diaphragm. This phenomenon of the hydraulic lock may be explained by the fact that the ampoule is desirably filled very near to capacity with the hypodermic liquid. Thus, it was possible for the initial collapsing movement of the top of the ampoule toward the diaphragm to increase the internal hydraulic pressure sufficiently to distort the diaphragm away from the point of the needle in order to compensate for the decrease in volume. Depending upon the amount of such distortion of the diaphragm, it could prevent puncturing of the diaphragm, and thereby prevent further collapsing of the ampoule to complete an injection. Unless the distance through which

the hypodermic needle had to travel before piercing the diaphragm and relieving internal pressure was small (e.g., under .015 of an inch in an ampoule having a volume of one cubic centimeter filled to 90% of capacity), it was possible for a hydraulic lock to cause rupturing of the peripheral seal between the diaphragm and the body, or even rupturing of the body itself, before an injection could be made. Even when the ampoules were not ruptured, it was found that in some instances an excessively great force was required to effect an injection.

The problem of preventing a hydraulic lock within the ampoule by providing for a minimum needle travel is complicated, however, by considerations of avoiding accidental piercing of the diaphragm and by practical limitations on its minimum thickness. More particularly, it is desirable to allow some clearance and consequent relative movement between the point of the needle and the diaphragm; otherwise, the needle may be inadvertently thrust through the diaphragm during handling of the ampoule prior to actual use. Further, from the standpoints of required strength of the ampoule to resist bursting and practical methods of manufacture, the thickness of the diaphragm cannot be less than approximately .010 inch, which thickness is a part of the distance the needle must travel before complete penetration of the diaphragm. It will thus be apparent that the desirability of providing clearance between the needle and diaphragm and the necessity of employing a diaphragm having a certain minimum thickness are opposed to providing as short a needle travel as possible in order to avoid a hydraulic lock.

Another problem associated with the use of hypodermic ampoules as previously proposed was the establishment of an effective liquid seal between the diaphragm and the skin. Such a seal is necessary to the proper functioning of the ampoule since, if intimate contact is not maintained between the skin and that portion of the diaphragm that is pierced by the hypodermic needle, some of the hypodermic liquid may squirt over the skin before the needle has been inserted therein. The loss of hypodermic liquid by such leakage cannot be tolerated since the amount of liquid which is injected is obviously critical and must be closely controlled. Moreover, ocurrence of this squirting action has been found to make the insertion of the needle into the skin more difficult.

It also is necessary to maintain a leakproof seal between the diaphragm and the needle where the needle penetrates the diaphragm during the injection so that a loss of the hypodermic liquid by leaking from the ampoule body around the periphery of the needle is prevented. This problem is made particularly difficult and troublesome because the relatively small cannular opening afforded by the hypodermic needle, as compared to the volume of liquid required to be exhausted in a brief period of time, contributes to the build up of hydraulic pressure in the ampoule which, in turn, tends to force the liquid to seep through the puncture in the diaphragm around the needle. The prevention of leakage during an injection is further complicated by the fact that the length of the seal which could heretofore be provided between the needle and the diaphragm was necessarily limited by the need for a diaphragm which is as thin as possible so as to be punctured by a short needle travel.

Inasmuch as the hypodermic ampoules to which the present invention relates are provided with hypodermic needles of fairly short length, an injection cannot be administered effectively unless the needle is guided to enter the skin in a substantially perpendicular position without canting or cocking. If this is not accomplished so that the hypodermic liquid reaches the tissue under the skin, the full effectiveness of the injection may not be realized, this being particularly likely when the injection is administered by manual collapsing of the ampoule by a relatively unskilled person. When the needle enters the skin at an angle, there is also the possibility that the skin will be painfully torn.

Other problems associated with the hypodermic ampoule construction as previously proposed are related to its manufacture and assembly and will be more fully discussed in connection with the detailed description of the present invention.

This invention is particularly concerned with improvements in the construction of hypodermic ampoules of the type heretofore described, and has for its main objective the provision of an ampoule body and diaphragm construction which effectively overcomes the above-discussed limitations and problems associated with the type of hypodermic ampoule described above, and to an improved technique of sealing the ampoule body and diaphragm so that they define a reservoir for reliably confining the liquid contents of the ampoule before and during an injection.

There is a need to provide a diaphragm construction which will always prevent the creation of a hydraulic lock when collapsing pressure is initially applied to force the hypodermic needle through the diaphragm, and to provide a new and improved ampoule body construction which facilitates a safe, efficient, and practical self administration of hypodermic injections by relatively unskilled and untrained persons.

There is also a need to provide an improved diaphragm for the hypodermic ampoule which effectively prevents any significant loss of hypodermic liquid due to leakage at the instant of initiation of the injection, as well as during its administration.

There is a further need to provide a

diaphragm possessing all of the characteristics described above and which additionally facilitates a safe, economical, and advantageous method of filling and assembling the ampoule.

There is also a need to provide an improved body construction for the hypodermic ampoule which is capable of discharging at least 90% of the contained hypodermic solution when subjected to a collapsing force of not more than 10 or 12 pounds.

There is a further need to provide an improved hypodermic ampoule construction in which the needle is guided for insertion substantially perpendicularly into the skin.

There is a still further need to provide a body construction and a diaphragm construction that are improved in the above respects while still being economical and practical to manufacture and assemble.

There is a further need to provide an inexpensive, rapid method of sealing the ampoule body to the diaphragm by utilizing localized or zone heating techniques.

There is a further need to provide an assembly for carrying out this heating method.

As contemplated by the invention, the improved ampoule diaphragm is formed with an integral, relatively rigid, generally cylindrical portion which constitutes a liquid sealing and needle guiding gland. This novel gland formation has an axial needle passage that is closed at one end by a thin, easily puncturable wall. When the ampoule body, diaphragm, and needle are assembled, a portion of the cannula of the needle adjacent its pointed end is slidably constrained in the needle passage of the gland with an interference fit and with the tip of the needle normally spaced from the puncturable wall at the end of the passage.

Because of the rigidity of the gland and the length over which it contacts the needle, an effective fluid seal is maintained around the cannula of the needle under the hydraulic pressures created during evacuation of the ampoule. At the same time, the needle movement is guided by the gland during the injection. This guided movement of the needle minimizes the possibility of its being canted or cocked and inserted at an oblique angle to the skin and/or failing to penetrate the skin to the required depth for an effective injection.

As further contemplated by the invention, the gland is surrounded by a thin, flexible wall portion which affords a bellows-like flexing action permitting movement of the gland axially inwardly of the ampoule to initiate relative penetrating movement of the needle through the puncturable wall of the gland when the ampoule is pressed against the skin. By reason of this movement of the gland, the hypodermic needle itself need only be moved a slight distance to pierce the diaphragm and relieve hydraulic pressure initially created within the ampoule. Consequently, it is possible to afford sufficient clearance between the tip of the needle and puncturable wall of the gland to avoid accidental puncture during handling of the ampoule, and, at the same time, to prevent the creation of a hydraulic lock during initiation of an injection.

In the preferred construction of the diaphragm, the flexible wall portion around the gland has at least one annular corrugation. As will hereinafter be made more apparent, the corrugated formation permits the gland to tilt sufficiently relative to the ampoule body to maintain a liquid seal with the skin thereby assuring a reliable injection even though carelessly administered.

The diaphragm comprising the invention also includes an annular, axially inwardly directed sealing rib or flange which is adapted to be tightly nested within the mouth of the ampoule body. During filling and assembly of the ampoule, this flange aids in locating the diaphragm with respect to the ampoule body so that the discharge end portion of the hypodermic needle can be quickly and accurately inserted within the needle passage of the gland. This flange also forms a temporary liquid seal for preventing the hypodermic liquid from spilling from the ampoule body prior to permanently sealing the diaphragm and body together at their peripheries.

In terms of structure, the ampoule body construction contemplated by the invention is comprised of a rigid upper end wall that merges into an at least partially conical, outwardly and downwardly flaring side wall. The side wall includes an upper flexible portion and a lower portion of larger diameter that is relatively more rigid and inflexible.

In the presently preferred embodiment of the invention, the upper and lower portions of the side wall are integrally connected to define the location of a primary hinge about which the upper part of the side wall folds downwardly under applied pressure to initiate collapsing thereof until the entire top section of the body has moved downwardly within the bottom section while the top section is being inverted.

The relative dimensions of the top and bottom sections of the body are controlled in relation to the volume of the ampoule so that, when it has been collapsed, the side wall portion of the inverted top section of the body is disposed closely adjacent the inner side wall surface of its bottom section and the upper rigid end wall of the ampoule is seated against the diaphragm. This collapsed configuration of the ampoule provides for a controlled evacuation of the hypodermic liquid well in excess of 90%. Further, the preferred type of collapse of the upper side wall as the top section of the body is inverted and moved within the bottom section enables the resulting high evacuation normally to be obtained with an applied force of only 4 or 5 pounds.

The improved ampoule contemplated by

the invention also is desirably constructed to minimize any tendency of the ampoule to aspirate the injected hypodermic liquid and/or natural body fluid back into the body after the injection has been made. This is preferably accomplished by providing a special hinge action around the upper end wall of the ampoule where it merges with the side wall. When the ampoule has been collapsed, the hinge at this location acts to lock the upper end wall tightly against the diaphragm and prevent the ampoule body from elastically expanding back toward its original shape and thereby creating a vacuum which would cause liquid to be sucked back into the body through the needle.

In order that the disclosure will be more fully understood and readily carried into effect, the following detailed description is given with reference to the accompanying drawings in which:

Figure 1 is a vertical cross-sectional view of a hypodermic ampoule embodying the shell and diaphragm construction of the present invention;

Figures 2, 3 and 4 are vertical cross-sectional views of the ampoule in use and illustrate successive stages in its evacuation;

Figure 5 is another vertical cross-sectional view of the ampoule in use and illustrates its configuration after the injection has been completed;

Figure 6 is a top plan view of the ampoule of Fig. 1;

Figure 7 is a fragmentary cross-sectional view of a portion of the body of the ampoule of Fig. 1;

Figure 8 is a bottom plan view of the ampoule illustrated in Figure 1;

Figure 9 is a fragmentary cross-sectional view of a portion of the ampoule diaphragm and needle;

Figure 10 is a vertical cross-sectional view of a modified embodiment of the invention;

Figure 11 is a vertical cross-sectional view of still another modified embodiment of the invention;

Figure 12 is a side elevation of the ampoule of Fig. 1, exploded to show the relationship of the parts when inserted in a die and subjected to heat according to the present method;

Figure 13 is a top plan view of a suitable induction ring which may be employed in the present method.

Reference is first made to Fig. 1 which illustrates a preferred construction of a hypodermic ampoule device. As shown, the hypodermic ampoule has a body portion 10 in the general form of an inverted cup-shaped shell defined by an upper end wall 11 and a circumferentially extending side wall. A peripheral, outwardly directed flange 13 integrally extends around the open end or mouth of the body 10, and to this flange 13 is peripherally sealed the disk-like diaphragm 14 of the invention so as to close the mouth of the body and form a fluid reservoir for containing a hypodermic liquid 12.

A hypodermic needle 15 is mounted entirely within the ampoule. The circular base or butt end 16 of the needle is clamped adjacent the inner surface of the upper end wall 11 by an annular, radially inwardly directed rib 17 so that the needle cannula 18 is disposed in axial alignment with the ampoule and has its pointed, discharge end 19 extending downwardly in position to be forced through the lower end of a gland or inner portion 20 of the diaphragm 14. A cannula opening (not shown) is formed through the needle base 16 so that the hypodermic liquid 12 can be evacuated from the ampoule through the needle after it has pierced the diaphragm.

As generally discussed above, the side wall of the body 10 is preferably comprised of a flexible upper portion 21 and a lower portion 22 of larger diameter that is relatively more rigid and inflexible. In the preferred embodiment of the ampoule shell illustrated in Figs. 1—7, the upper side wall portion 21 is conical with a slight outward and downward inclination from the upper end wall 11, while the lower side wall portion 22 is substantially cylindrical. The upper and lower portions of the side wall are integrally joined by a short, thin, circumferential shoulder 23.

As shown, the relative wall thicknesses of the side wall of the preferred embodiment of the ampoule body 10 are such that, when axially directed pressure is applied, the relatively rigid and inflexible lower portion 22 will remain substantially undistorted and the more flexible upper portion 21 will fold and progressively roll on itself until the top section of the body, designated T in Fig. 1, is inverted within the confines of the bottom section, designated B. To this end, the upper portion 21 of the side wall is made as thin as possible to permit an easy folding and rolling action and still retain sufficient strength to resist fracture or bursting and tearing. It is also preferred to taper this portion of the side wall from a maximum thickness at its upper end to a minimum thickness at its lower end.

The lower portion 22 of the side wall of the ampoule body may have a thickness approximately twice the maximum thickness of the upper side wall portion. The shoulder 23 between the two upper and lower portions is no thicker and is preferably slightly thinner than the minimum thickness of the upper side wall portion so as to define a primary hinge at which collapsing of the side wall is controllably initiated.

In order to accomplish the objective of obtaining the maximum discharge of substantially all of the hypodermic liquid contained in the ampoule, it has been found necessary, in the body construction described, to maintain a ratio between the height X (Fig. 1) of the

lower side wall portion 22 and the total height Y of the side wall of the body which will permit the upper end wall 11 of the body to bottom against the diaphragm 14 and the upper side wall portion 21 to turn inside-out and lie closely adjacent the inner surface of the lower side wall portion 22. If this ratio is too small and the height X of the lower side wall portion 22 is substantially less than the height Z of the upper portion 21, the upper portion will not lie against the inside surface of the lower portion when the ampoule body is collapsed. Conversely, if the ratio of the height X of the lower portion to the total height Y of the side wall is too large, the upper end wall of the body will not be able to bottom against the diaphragm 14. The optimum height ratio of the lower portion of the side wall to the total side wall depends upon the volume of the ampoule, the material of which the body 10 is made, the relative wall thicknesses the length of the shoulder 23, and other design details and will vary accordingly. However, in the particular embodiment of the ampoule shell illustrated in Figs. 1—7, it has been found that the height X of the lower wall portion 22 should exceed the height Z of the upper wall portion 21 and preferably should be in the range of from 50 to 60% of the total side wall height Y.

Referring particularly to Fig. 7, it will be seen that the ampoule body is further provided with a circumferential notch or groove 24 adjacent the upper end wall 11. As will be more fully explained, this notch 24 defines the location of a secondary hinge which permits the top body section T of the shell to be inverted and nested within the bottom section B with the upper end wall of the body locked against the diaphragm.

Reference is now made to Figs. 2, 3, 4 and 5 which illustrate progressive stages in a collapsing of the ampoule body. It will be seen in Fig. 3, that when pressure is applied to the upper end wall 11, as by pressing with the thumb, the shoulder 23 defines the initial location of a primary hinge about which the side wall is folded to initiate collapsing thereof. Continued application of pressure forces the flexible upper side wall portion 21 to progressively roll downwardly on itself until it is substantially turned inside-out and telescoped within the bottom section 22, as illustrated in Fig. 4.

With still continued application of pressure, the secondary hinge at the notch 24 is closed and the top shell section T is turned completely inside-out and inverted, with the end wall 11 bottomed against the diaphragm 14 within an annular rib 25 (Fig. 5).

Considering both Figs. 4 and 5, it will be seen that bending at the secondary hinge by closing of the notch 24 has the effect of partially relieving the reverse bend 26 (Fig. 4) momentarily formed in the side wall of the body around the upper end wall 11 by the final stage of downward collapsing movement of the upper side wall portion. As this reverse bend 26 is relieved, the secondary hinge defined by the notch 24 bends through and beyond a dead center position so that the body section T is turned completely inside-out and elastic stresses tending to return it toward its original shape are relieved. In fact, the action of passing through a dead center position at the location of the secondary hinge as the secondary hinge is closed provides a locking action by which an elastic force is created that urges the upper end wall 11 downwardly against the diaphragm 14. The elasticity of the ampoule body 10 is thereby utilized to resist return toward its original shape. Thus, it will be seen that the provision of the secondary hinge minimizes the possibility of aspiration, since there is little chance for a vaccum to form in the ampoule body atfer the hypodermic liquid has been evacuated.

The relative heights of the upper and lower portions of the side wall are carefully controlled, as previously discussed, so that, when the top section T of the shell has been completely inverted by closing of the secondary hinge notch 24, the upper end wall 11 is seated against the diaphragm 14 (Fig. 5), and the resulting configuration of the collapsed ampoule shell resembles one cup nested within another. This collapsed form of the ampoule shell assures that at least 90%, and usually from 95 to 97%, of the hypodermic liquid will have been discharged during the injection.

The rolling action by which the side wall of the ampoule body initially folds about the primary hinge 24 and the flexible upper side wall portion 21 progressively rolls downwardly upon itself and turns inside-out against the inner surface of the lower portion 22 requires a relatively small force to be applied to the ampoule. In most instances, a force of 4 or 5 pounds, or approximately the force exerted by a firm hand shake, is sufficient to collapse the body and discharge the liquid in the course of an injection. The rolling, collapsing action by which the ampoule body is collapsed acts in conjunction with the previously mentioned gland 20 to provide the additional advantage of preventing the needle from cocking as it is thrust through the diaphragm 14 into the skin. It will be understood that the liquid passes through the opening of the needle base 16 (not shown) into the small cavity behind the base and from there into the base of the needle.

Reference is now made to Fig. 10 which illustrates a modified embodiment of the hypodermic ampoule body construction comprising the present invention. As in the case of the preferred embodiment of the ampoule shell of Figs. 1—7, the ampoule generally includes a body 50 in the form of an inverted cup that is defined by an upper end wall 51 and a circumferentially extending side wall. A

diaphragm 52, which generally corresponds to the diaphragm 14, extends across the mouth of the cup-shaped body 50 and is sealed to the peripheral flange 53.

For purposes to be more fully explained, the annular rib 55, which integrally extends from the upper surface of the diaphragm 52 into the mouth of the ampoule body, may be made of greater height than the previously mentioned rib 25 of the diaphragm 14 shown in Figs. 1—5. As is apparent from Fig. 10, when the rib 55 is pressed into the mouth of the ampoule body 50, the rib engages a substantial portion of the inner side wall surface of the body to effectively thicken and strengthen that portion of the side wall. In this assembled position of the diaphragm 52, the rib 55 may be thus considered as forming part of the lower portion of the circumferential ampoule body side wall and the radially inward, sloping surface 56 of the rib may be considered, in effect, as being a lower, inner side wall surface of the ampoule body.

A hypodermic needle 57 (only a portion of which has been shown for the sake of clarity) corresponds to the needle 14 in Figs. 1—4 and is similarly mounted within the body 50 by an integral, radially inwardly extending rib 58. The opposite, pointed end portion (not shown) of the needle is slidably constrained within the gland 59.

In the modified body construction of Fig. 10, the entire circumferentially extending side wall (excluding the functionally integral rib 55 of the diaphragm) is conical and has an outward and downward inclination from the upper end wall 51. The thickness of the side wall substantially uniformly tapers from a minimum thickness at the upper end wall 51 to maximum thickness at the mouth of the ampoule body.

In order to provide for the desired collapsing action of the body 50, wherein an upper portion of the side wall is caused to progressively roll on itself and turn inside-out against the inner surface of a lower part of the ampoule, the top of the ampoule body is formed with an external, circumferential notch 60. This notch 60 defines a thin, flexible shoulder 61 at the upper end of the circumferentially extending side wall of the ampoule body. The shoulder 61 is no thicker and is preferably slightly thinner than the minimum thickness of the tapering side wall and thus constitutes the primary hinge at which collapsing of the side wall is controllably initiated.

A second circumferential notch or groove 62 is formed in the outside surface of the side wall of the ampoule body 50 between the top and the bottom of the side wall. The side wall thickness of the ampoule body at the notch 62 is slightly greater than the thickness of the shoulder 61 so as to form a secondary hinge that aids in locking the upper end wall 51 against the diaphragm 52 after the ampoule body has been collapsed.

The notch 62 divides the ampoule body into a top section T_1 and a bottom section B_1, which are respectively defined by an upper portion 63 of the circumferentially extending side wall and a lower portion 64 of the side wall. Inasmuch as the ampoule side wall is generally conical and has a tapering thickness decreasing from its top to its bottom, the upper side wall portion 63 is relatively flexible, and the lower side wall portion 64, which is further reinforced by the functionally integral rib 55 of the diaphragm, is relatively more rigid and inflexible and has a larger diameter. These relative wall thicknesses are such that the upper side wall portion 63 will roll on itself when axially directed pressure is applied to the ampoule body, while the lower side wall portion 64 will remain substantially undistorted.

As in the case of the previously described, preferred embodiment of the invention, the relative heights X_1 and Z_1 of the upper and lower side wall portions 63 and 64, respectively, are carefully controlled to assure that substantially all of the hypodermic liquid 12 can be discharged by collapsing the ampoule body. More particularly, the ratio of the height X_1 of the lower side wall portion 64 to the total height Y_1 of the ampoule body is such that the upper end wall 51 will seat against the diaphragm 52 and the upper side wall portion 63 will lie against the radially inner surface 56 of the diaphragm rib 55 when the ampoule is collapsed.

The progressive stages of deformation of the ampoule body 50 as it is collapsed are schematically indicated by dot-dash lines in Fig. 10. After pressure has been initially applied to the upper end wall 51 to start penetrating movement of the hypodermic needle 57 through the diaphragm 52, the shoulder 61, which constitutes the primary hinge in this embodiment, is folded or bent downwardly to initiate collapsing of the circumferential side wall. Thereupon, the relatively flexible upper side wall portion 63 is caused to progressively roll downwardly on itself toward the notch 62, as indicated by the upper dot-dash lines in Fig. 10, until the upper side wall portion 63 is substantially turned inside-out, as indicated by the lower dot-dash lines in Fig. 10.

In the last stage of collapsing movement, the upper end wall 51 is forced against the diaphragm 52 to completely and telescopically invert the top body section T_1 within the bottom body section B_1, with the flexible upper side wall portion 63 disposed against the inner surface 56 of the diaphragm rib 55. The illustrated construction of the rib 55, wherein its radially inner surface 56 slopes axially inwardly of the ampoule body from the notch 62

toward the mouth of the body is of advantage since it assures maximum evacuation of the hypodermic liquid by filling the space between the inverted wall portion 63 and the lower wall portion 64 and thus preventing liquid from being trapped therebetween. However, it will be apparent that this same effect could be achieved by forming the body section B_1 so that its lower side wall portion 64 has an axially inwardly and downwardly sloping inner surface.

As the ampoule body is finally collapsed, the secondary hinge at the notch 62 opens up to minimize elastic stresses in the folded part of the side wall that would tend to cause the side wall to unfold and the ampoule body to return toward its original shape.

In addition to defining the location of the primary hinge 61, the notch 60 acts similarly to the notch 40 previously described in conjunction with the preferred embodiment of the invention by providing a locking action wherein the upper end wall 51 is urged against the diaphragm 52 when the ampoule has been finally collapsed. When the shoulder 61 is folded downwardly to initiate collapsing of the side wall of the ampoule body, the notch 60 is closed and the shoulder 61 is bent through a dead center position. This movement of the shoulder through a dead center position effectively creates an elastic force in the material of the shoulder that urges the upper end wall 51 downwardly so that, when the notch 62 has been opened to relieve oppositely acting stresses in the fold of the side wall, the upper end wall will be effectively locked against the diaphragm and prevented from returning toward its original position.

Reference is next made to Fig. 11 which illustrates still another embodiment of the ampoule body. The body 70 of the ampoule is again substantially in the form of an inverted cup including an upper end wall 71 and a circumferentially extending side wall. Reference numeral 72 designates a diaphragm that corresponds in structure to the diaphragm 14 illustrated in Figs. 1—5 and similarly extends across the mouth of the body and is sealed to a peripheral flange 73.

A hypodermic needle 75 (only a portion of which has been shown for the sake of clarity) is disposed entirely within the ampoule body in axial alignment therewith. The base of the needle is clipped adjacent the upper end wall 71 of the body by a radially inwardly extending rib 76, and the opposite, pointed end portion (not shown) of the needle is slidably constrained within the gland 77. The base of the needles of the embodiments illustrated in Figs. 10 and 11 is also provided with an opening to allow passage of the liquid into the base of the needle.

As in the case of the embodiment illustrated in Fig. 10, the ampoule body 70 is formed with an external, circumferential notch or groove 83 at the upper end of the side wall. This notch 83 defines a relatively thin and flexible shoulder 84 which is no thicker and is preferably slightly thinner than the minimum thickness of the side wall and thus constitutes a primary hinge at which collapsing of the side wall is controllably initiated.

A second circumferential notch or groove 85 is formed in the inner side wall surface of the ampoule body between the upper end wall 71 and the mouth of the body. This notch 85 divides the ampoule body into a top body section T_2 that is defined by a relatively flexible upper side wall portion 86 and a bottom body section B_2 that is defined by a relatively inflexible and rigid lower side wall portion 87. The side wall thickness at the notch 85 may be slightly thicker than the shoulder 84 so as to form a secondary hinge which aids in locking the upper end wall 71 against the diaphragm 72 by relieving elastic stresses created in the side wall.

The flexible upper side wall portion 86 is conical with an outward and downward inclination from the upper end wall 71 and has a wall thickness that preferably tapers from a minimum thickness at the notch 83 to a maximum thickness just above the notch 85. The relatively inflexible and more rigid lower side wall portion 87 may be substantially cylindrical and is formed to have an inner side wall surface 89 that slopes axially inwardly of the ampoule body from the notch 85 toward the mouth of the body. This sloping inner surface 89 of the side wall portion 87 provides the same beneficial effect as the rib construction 55 shown in Fig. 10 by preventing hypodermic liquid from being trapped in the ampoule body when it has been colapsed. The relative side wall thicknesses of the ampoule body are such that the upper side wall portion 86 can be rollingly turned inside-out when axial pressure is applied to the ampoule, while the lower side wall portion 87 will remain substantially undistorted.

In accordance with the previously described embodiments of Figs. 1—7 and Fig. 10, the relative heights X_2 and Z_2 of the upper and lower side wall portions 86 and 87, respectively, are controlled to achieve maximum discharge of the hypodermic liquid. To this end, the location of the notch 85 is such that the ratio of the height X_2 to the total height Y_2 of the side wall will permit the upper end wall 71 to be seated against the diaphragm and the inverted upper side wall portion 86 to lie against the sloping inner surface 89 of the lower side wall portion.

The collapsing action of the ampoule 70 is generally similar to that discussed in connection with the structure of Fig. 10 and is schematically indicated in Fig. 11 by the dot-dash lines. After pressure has been initially applied to start penetrating movement of the needle 75 through the gland 77 of the

diaphragm, the shoulder 84, which constitutes the primary hinge in this embodiment, is bent downwardly to initiate folding and collapsing of the side wall. During this initial bending movement, the notch 83 is closed and the shoulder 84 is moved through a dead center position. An elastic force is thereby created in the material of the shoulder and this elastic force tends to further urge the upper end wall 71 toward the diaphragm 72.

Continued axial pressure on the ampoule causes the relatively flexible upper side wall portion 86 to progressively roll inside-out, as indicated by the upper dot-dash lines in Fig. 11, and the fold in the upper side wall portion to move toward the notch 85. In this particular embodiment of the invention, the upper side wall portion 86 may bow or flex outwardly a slight amount as it is rolled downwardly; however, the characteristic ease with which the upper side wall portion may be inverted is not significantly different from that exhibited by the other embodiments of the invention.

In the final stage of collapsing movement, the upper end wall 71 is seated against the diaphragm 72 and the top body section T_2 is completely telescopically inverted within the bottom body section B_2 with the flexible side wall portion 86 against the inner surface 89 of the lower side wall portion 87. As this position is reached, the notch 85 is closed to locate the downward bend or fold of the side wall. As noted above, this minimizes the elastic stresses in the folded part of the side wall and thus the tendency of the side wall to unfold and the ampoule body to return toward its original shape.

As in the preferred embodiment of the invention, it will be seen that the modified embodiments of Figs. 10 and 11 provide for the rolling action by which an upper portion of the side wall of the ampoule body is caused to roll downwardly as the ampoule is collapsed and to turn inside-out against the inner surface of a lower side wall portion. This rolling and inverting action has been achieved by the provision of primary and secondary hinges which enable the ampoules to be controllably collapsed by a relatively small axial force. At the same time, the modified ampoule body constructions assure that very nearly all of the hypodermic liquid can be discharged during an injection.

Referring now to the detailed, preferred construction of the diaphragm 14, its generally disk-like configuration is shown to be defined by a substantially flat, annular, outer portion 100, a generally cylindrical inner portion 20, and a relatively thin and flexible, annular, intermediate portion 101 connecting the inner and outer portions to permit relative movement therebetween.

The annular outer portion 100 of the diaphragm is heat-sealed to the flange 13 of the body 10 to form a leakproof and moisture-proof seal. In this assembled position, the diaphragm extends across the mouth of the ampoule body to form a lower end wall opposite the upper end wall 11.

To facilitate filling and assembling the ampoule, the outer portion 100 of the diaphragm is preferably formed with the previously mentioned, integral, annular rib 25 which extends above the upper surface of the diaphragm, as viewed in the drawings. This rib 25, which may be of triangular cross-section, is formed on a diameter slightly exceeding the inner diameter of the open bottom or mouth of the ampoule body so that the rib may be snugly nested within the mouth of the body 10 with an interference fit.

The generally cylindrical inner portion 20 of the diaphragm 14 constitutes a needle guiding and liquid sealing gland having an axial needle passage 102 extending into the upper end of the gland from inside the ampoule body 10. As shown most clearly in Fig. 9, the needle passage 102 terminates short of the opposite, lower end of the gland to form a relatively thin, easily puncturable wall 103 which normally closes the bottom or lower end of the passage. In order to facilitate entry of the pointed discharge end 19 of the hypodermic needle into the passage 102 when the rib 25 of the diaphragm is pressed into the mouth of the body 11, the upper inner end of the gland may be recessed, as generally designated by reference number 104.

The diameter of the passage 102 is slightly less than that of the needle cannula 18 so that the needle may be disposed with a portion of its cannula slidably constrained within the passage with an interference fit. In order to maintain this sliding interference fit of the needle 15 within the passage 102 under the hydraulic pressures created by collapsing the body 10, the wall thickness of the gland is made relatively thick as compared to the rest of the diaphragm so that the gland is a relatively rigid body resistant to deformation.

The axial distance over which the gland 20 engages the needle 15 is sufficiently great to maintain an effective liquid seal around the needle cannula 18 after the needle has penetrated the thin wall 103 at the bottom of the passage 102, thereby preventing the hypodermic liquid from seeping through the punctured diaphragm around the periphery of the needle. In general, in a device designed for relatively shallow, subcutaneous injections, the axial length of this seal after the needle has punctured the diaphragm wall 103 may be approximately three to five times the diameter of the cannula 18 of the needle.

Referring particularly to Figs. 1 and 9, it will be seen that, in the normal assembled position of the needle, its pointed discharge end 19 is spaced from the puncturable wall 103 at the bottom of the passage 102. The purpose of this clearance is to allow for a certain

amount of relative movement between the needle 15 and the diaphragm 14 before the pointed end 19 of the needle can contact and begin to penetrate the thin wall 103. In this way, the diaphragm is protected against accidental puncture during shipping, storing, and handling of the ampoule prior to actual use.

To prevent the formation of a hydraulic lock during initiation of an injection, the lower or bottom end of the gland 20 is normally disposed below the lower surface of the outer annular diaphragm portion 100, desirably by a distance at least equal to the space between the end 19 of the hypodermic needle and the puncturable wall 103, so that relative movement of the needle into contact with the puncturable wall can be effected merely by pressing the bottom of the gland 20 against the skin to move the gland axially inwardly of the ampoule body 10. In the preferred construction of the diaphragm 14, the normal projection of the bottom or lower end of the gland below the diaphragm portion 100 is made great enough to assure complete penetration of the wall 103 by the needle end 19 when the gland is inwardly moved with respect to the ampoule body by pressure of the gland against the skin.

In order to provide for relative movement between the gland 20 and the outer diaphragm portion 100 so that the gland may be moved inwardly of the ampoule body, the connecting, annular, intermediate diaphragm portion 101 is made as thin as possible to exhibit a high degree of flexibility and still resist rupturing and tearing during the administration of an injection. Because of the flexibiilty afforded by this part of the diaphragm, which preferably is thinner than the thinnest wall section of the ampoule body 10, the gland 20 usually may be moved to initiate penetration of its wall 103 with an applied force of not more than one or two pounds. During this relative movement between the gland 20 and the outer portion 100, some of the thinner portions of the body 10 and/or the diaphragm 14 may be distorted outwardly. No attempt has been made to illustrate this distortion, since the exact points of distortion would obviously be speculative.

As most clearly illustrated in Fig. 9, the intermediate diaphragm portion 101 is preferably formed with one or more annular corrugations 105 and 106 to give it a bellows-like action, permitting axial movement of the gland 20. The provision of at least one annular corrugation also permits the gland 20 to be axially canted with respect to the ampoule body 10 if the ampoule body should not collapse uniformly and the needle should be tipped out of its desired axial alignment with the ampoule. This is of advantage in assuring a reliable injection, even though carelessly administered, since the bottom of the gland will remain seated in liquid sealing contact with the skin when its axis is cocked at an angle of as great as 20 degrees from a perpendicular to the skin.

Reference is now made to Figs. 2—5 which illustrate progressive stages of deformation of the diaphragm 14 as the ampoule is collapsed to administer an injection. As described above, the ampoule is used by seating the diaphragm against the skin and applying axial pressure to the upper end wall 11 to force the hypodermic needle through the diaphragm into the skin and discharge the hypodermic liquid.

When pressure is first applied to the upper end wall 11, the bottom or lower end of the gland 20 is pressed against the skin S and the gland is caused to move inwardly of the ampoule (Fig. 2) because of the relative flexibility of the intermediate portion 101 of the diaphragm as compared to the rest of the ampoule. The amount of hypodermic liquid displaced by the slight inward movement of the gland is small and may be accommodated by the previously mentioned deformations of the body 10 and/or diaphragm 14. In this manner, penetration of the pointed discharge end 19 of the needle through the wall 103 is initiated without creating a high internal hydraulic pressure and a consequent hydraulic lock.

Continued application of pressure to the top of the ampoule (Fig. 3) produces additional inward movement of the gland 20 and also initiates collapsing of the ampoule body 10 about the hinge 23 and downward movement of the needle 15 through the gland so that the pointed discharge end 19 of the needle is inserted into the skin S. Because of the freedom of movement which is afforded to the gland by the corrugated construction of the intermediate diaphragm portion 101, the lower end of the gland is firmly seated against the skin even though the pressure on the ampoule is off-center so as to cock the entire ampoule and tilt its axis at an angle to a perpendicular to the normal plane of the skin. This seating action of the gland against the skin and the guided movement of the hypodermic needle through the passage 102 makes it possible to insert the needle substantially perpendicularly into the skin even under these conditions, without an undesirable squirting of the hypodermic liquid over the skin after the discharge end 19 of the needle has penetrated the gland wall 103.

If desired, the lower end of the gland may be formed with a depending, skin-contacting, annular rib 107. As shown in Fig. 3, this rib acts to depress the skin so that the skin bulges upwardly within the confines of the rib, as generally designated by reference numeral 108, into closer proximity to the wall 103, but short of contact therewith. By holding the skin so that it is slightly out of contact with the gland at the point where the skin is to be punctured, the danger of con-

taminating this area and resultant infection are minimized.

It will be apparent from the foregoing that the diaphragm construction of the invention contributes in many ways to a reliably functioning hypodermic ampoule and permits the administration of an injection with a minimum of applied force and with substantially no leakage of the hypodermic liquid.

In addition to these advantages, the formation of the gland 20 facilitates injection molding of the plastic diaphragm. More particularly, the relatively large mass of the gland permits the relatively thin portions 100 and 101 of the diaphragm to be perfectly formed in high speed, injection molding machines with a minimum amount of scrap.

The hypodermic ampoule, including the body 10 and the diaphragm construction 14, may be made of any flexible material which is inert and retains its strength when exposed to the hypodermic liquid and which will not rupture and/or tear as the ampoule is collapsed. Suitable materials include tough, but yet relatively flexible elastomeric compounds, including plastics such as polyethylene and various other polyvinyl compounds and the like; plastic coated metal foils, and uncoated metal foils which may be joined to form a leakproof liquid seal.

When the ampoule is made of plastic, an effective, tight seal may be formed between the ampoule body 10 and the diaphragm 14 by the following heat sealing technique. An ampoule body, filled with hypodermic liquid is inserted in an inverted position into a lower clamping die member 134. The lower clamping die member 134 is made of a non-conductive material such as material available under the Trade Mark "Teflon" (tetrafluoroethylene resin) or nylon (a long-chain polymeric amide having recurring amide groups as an integral part of the main polymer chain) and has a horizontal bite portion 135 adapted to receive the flange 13 of the ampoule body 10. A cylindrical bore 136 is provided in the die member 134 having a diameter slightly greater than the outside diameter of the bottom side wall portion 22 of the ampoule body 10 to provide for easy insertion of the body 10 therein.

According to one aspect of this invention, the circumferential flange 13 is preferably formed with an annular groove 137 in which is seated an electrically conductive member 138. The member 138 is preferably a ring made of stainless steel such as A.I.S.I. (American Iron and Steel Institute) type 410 martensitic or A.I.S.I. (American Iron and Steel Institute) type 304 austenitic stainless steel. The latter steel is employed where corrosion is a problem and the former steel is employed where ease of fabrication is desired and corrosion is not a substantial problem. In the preferred form of this invention, the conductive member 138 is a flat, annulus.

After the conductive member 138 is inserted into the annular groove 137, the diaphragm 14 is placed over the mouth of the ampoule body 10 and forms a junction with the flange 13 of the ampoule body 10. As noted above, the rib 25 aids in locating the diaphragm 14 with respect to the body 10 and serves as a temporary liquid seal.

An upper clamping die 139 which is relatively movable toward and axially aligned with the lower clamping die 134 is then brought in pressure exerting contact with an annular flange portion 140 of the diaphragm 14, and in cooperation with the lower clamping die 134, serves to exert pressure on the flange area to be sealed. Similar to the lower clamping die 134, the upper clamping die 139 is made of a non-conductive material such as material available under the Trade Mark "Teflon" or nylon and has a horizontal bite portion 141 adapted to engage the flange 140 of the diaphragm 14.

While the assembly is held in this position and while pressure is applied to the cooperating flanges of the ampoule body 10 and the diaphragm 14, an induction coil 142, preferably of the type shown in Fig. 13, is placed over the die halves and is held in the position shown in Fig. 12, substantially in the plane defined by the electrically conductive member and the bite portions of the dies. High frequency current is passed through the coil 142, thus exciting and thereby heating the conductive member 138. By controlling the current in the induction coil 142, the outer and inner edges of the conductive member 138 are heated to a temperature sufficient to heat the surrounding plastic slightly above the fusion temperature of the plastic while the needle 15, which is relatively remote from the inner periphery of the induction coil, remains relatively cool. The current in the induction coil should be maintained for a period long enough to fuse the plastic immediately surrounding the conductive member 138, but not long enough to transmit deleterious heat from the conductive member 138 to the hypodermic liquid 12 or to the plastic walls of the ampoule body 10 and the diaphragm 14 that define the reservoir portion of the ampoule, since excessive heat may harmfully affect the medicant contained in the ampoule and/or seriously weaken the wall structure thereof. Although the temperature of the needle is increased slightly, this temperature rise is not sufficient to transmit deleterious heat to the plastic ampoule or to the medicant contained therein.

Ideally, it is desirable to heat the entire conductive member 138 to the desired temperature at a uniform rate to effect uniform fusion of the surrounding plastic and provide a tight seal. In practice, however, the outside

diameter of the conductive member 138 would be heated more rapidly than the inside diameter because of the greater flux density in the region of the outside diameter. It is desirable therefore to reduce the difference between the inside and outside diameters of the conductive member 138 as much as is practicable consistent with manufacturing procedures.

The heat sealing method according to the present invention is not limited to the use of a solid ring of stainless steel for the electrically conductive member as is set forth above. Any electrical conductor capable of emitting heat on excitation by an induction heating coil is obviously adaptable to the disclosed process. Successful heat seals have been attained by employing a printed circuit with metallic ink or powdered metal in the joint defined by the flange portions of the ampoule body 10 and the diaphragm 14. An effective and tight heat seal has been produced between an ampoule body and a diaphragm by the following procedure.

After the ampoule body is filled with hypodermic liquid, an annular ring of stainless steel approximately 0.008 inch thick and having an outside diameter of 0.910 inch and an inside diameter of 0.730 inch is placed in the annular grooves provided in the ampoule body flange. The diaphragm is then placed over the mouth of the ampoule body and pressure is applied to the flange portions by a pair of electrically non-conductive dies. An ultra high frequency current of 1,200,000 cycles per second is passed through an induction coil surrounding the dies and adjacent to the flange portion. The total heating and cooling time to attain a satisfactory heat seal is $\frac{1}{3}$ second. During this period, heat sufficient to fuse the plastic is localized within a zone extending 0.005 inch to 0.01 inch beyond the inner and outer edges of the ring. No deleterious heating of the medicant or weakening of the surrounding plastic was detected upon inspection of the sealed ampoule.

The invention is not limited to the provision of a metallic ring at the joint to be sealed. A suitable plastic or other material may be employed which has a dielectric constant greater than that of the material of the ampoule body and diaphragm. When a dielectric heat sealing technique is employed, the dielectric material is placed in the junction to be sealed and suitable annular electrodes are placed on either side of the flange area to be sealed. A frequency of about 1,200,000 cycles per second may be employed for the dielectric technique.

According to a still further aspect of this invention, the junction defined by the flange portions of the ampoule body 10 and the diaphragm 14 may be sealed ultrasonically. In this case, the annular groove 137 is not provided and according to this aspect of the invention the mating surfaces which define the joint between the flange portions of the ampoule body 10 and the diaphragm 14 are substantially flat. After the ampoule body is filled with hypodermic liquid the diaphragm is placed over the mouth of the ampoule body. The ampoule body is inserted into a lower backing die which may be similar in configuration to the lower die member 134 shown in Figure 12. An upper die having a horizontal bite portion, which may be similar to the horizontal bite portion 141 of the upper clamping die 139, is brought into engagement with the flange 140 of the diaphragm 14. A suitable transducer is brought into engagement with the upper end portion of the upper die and is vibrated at a frequency of 20,000 cycles per second and an amplitude of .005 inch. The energy produced by the transducer is transmitted through the upper die and excites the molecules of the flange area to be sealed. This excitation results in a highly localized heating of the area to be sealed and the area is heated to a temperature of about 350°F., to 400°F., in 0.7 second. The localized heat produced by this ultrasonic technique is sufficient to fuse the joint without harmfully affecting the medicant contained in the ampoule or seriously weakening the wall structure thereof.

The terms "upper", "lower", "bottom", "top", and so forth have been used herein merely for convenience in the foregoing specification and in the appended claims to describe the hypodermic ampoule and its parts as orientated in the drawings. It is to be understood, however, that these terms are in no way limiting to the invention since the ampoule may obviously be disposed in many different positions when it is used.

WHAT WE CLAIM IS:—

1. A hypodermic injection device including a collapsible, generally cup-shaped, hollow body having an upper end wall and a circumferentially extending side wall, a closure member peripherally joined to said body across its mouth, said closure member forming a lower end wall and closing the body, and a hypodermic needle enclosed within the body and mounted on said upper end wall, said needle having a cannula extending from said upper end wall with a pointed end directed toward said lower end wall to puncture the same and permit the cannula to be thrust therethrough when the hypodermic injection device is collapsed by movement of said upper and lower end walls toward each other, said hollow body including a primary hinge portion at which circumferential bending thereof is initiated upon movement of said upper end wall toward said lower end wall so as to turn an upper portion of the side wall inside out as said hollow body is collapsed, and said upper end wall and upper portion of said side wall are shaped and dimensioned to nest within the lower portion of the hollow body when it has been collapsed, with the upper end wall sub-

stantially covering the lower end wall at the lower mouth of the body.

2. A hypodermic injection device according to claim 1 wherein the lower end wall includes guiding means engaging and constraining the cannula of the needle to guide its travel toward the portion of the lower end wall to be penetrated thereby when said upper and lower end walls are moved toward each other.

3. A hypodermic injection device according to claim 1 wherein the lower end wall comprises an outer, annular portion, an inner portion, and a relatively thin and flexible, annular, intermediate portion connecting said inner and outer portions to permit relative movement thereof.

4. A hypodermic injection device according to claim 1 wherein the lower end wall comprises an outer, annular portion, a relatively thick inner portion, and a relatively thin and flexible, annular, intermediate portion connecting said inner and outer portions to permit relative movement thereof, said inner portion having a needle passage extending into its upper surface and terminating short of its lower surface, and the pointed end portion of the nedle cannula being slidably received and constrained within said passage with its pointed end normally spaced from the terminal end of the said needle passage.

5. A hypodermic injection device according to claim 4 wherein the closure member is a substantially flat diaphragm and the lower surface of said inner portion thereof projects below the lower surface of the remainder of the diaphragm for a distance at least equal to the space between the pointed end of the needle and the terminal end of said needle passage.

6. A hypodermic injection device according to any of claims 3 to 5 wherein the intermediate portion of said closure member is configured to provide at least one annular corrugation around said inner portion of the diaphragm to facilitate relative movement of the inner and outer portions of the closure member.

7. A hypodermic injection device according to any of the preceding claims wherein the closure member is configured to provide an integral rib spaced inwardly from and extending above the adjacent surface of the periphery of the closure member, said rib being received within the mouth of said body with an interference fit against the inner surface of said side wall thereof.

8. A hypodermic injection device according to any of the preceding claims wherein the body has an annular flange extending outwardly from the side wall of the body at the mouth thereof and said flange and a mating annular portion of said closure member are sealed one to the other closely adjacent the junction of said side wall and flange of the body.

9. A hypodermic injection device according to any of the preceding claims wherein the body comprises a top section and an integrally connected bottom section, said top section including said upper end wall and an upper portion of said side wall, and said bottom section comprising the remaining lower portion of said side wall, said lower portion of said side wall being of greater diameter than the upper portion of said side wall and being from about 50% to about 60% of the total height of the side wall, whereby, when the body is collapsed in an axial direction by pressure on said upper end wall, said top section of the body may be turned inside-out to invert the same while moving it into the confines of the bottom section of the body to substantially fill the bottom section.

10. A hypodermic injection device according to claim 9 wherein the upper end wall of the body is relatively rigid and inflexible compared to said upper portion of said side wall.

11. A hypodermic injection device according to claim 9 or claim 10 wherein the body includes a relatively flexible, annular, side wall portion defining a primary hinge located between the top section and the bottom section of said body at which folding of the side wall will be initiated upon collapsing the body by endwise pressure on said upper end wall.

12. A hypodermic injection device according to claim 9 or claim 10 wherein the side wall of the body comprises a relatively flexible, annular, portion located between the top section and the bottom section of said body constituting a zone of reduced resistance to folding during collapsing of the body.

13. A hypodermic injection device according to claim 9 wherein the upper portion of the side wall of the body is relatively flexible for progressively bending and rolling on itself from one end to the opposite end thereof so as to turn said top section of the body inside-out and invert the same while moving it into the confines of the bottom section of the body, said lower portion of said side wall being relatively more rigid and inflexible than said upper portion of said side wall so as to resist folding when the body is collapsed in an axial direction by pressure on said upper end wall.

14. A hypodermic injection device according to any of claims 9 to 13 wherein the side wall has an annular portion of maximum flexibility at one end of said upper side wall portion for defining a primary hinge at which bending of said side wall will first occur in response to axial pressure on said upper end wall so as to cause progressive bending and rolling of said upper side wall portion on itself from said one end thereof to the other end thereof.

15. A hypodermic injection device according to claim 14 wherein the side wall includes another relatively flexible annular wall portion at said other end of said upper side wall portion for defining a secondary hinge that

relieves elastic stresses in the side wall created by progressively bending and rolling the upper side wall portion from said primary hinge to said secondary hinge.

16. A hypodermic injection device according to claim 14 wherein the annular portion of the side wall of the body constituting the primary hinge extends radially inwardly of the body between the upper and lower side wall portions thereof.

17. A hypodermic injection device according to claim 14 wherein the annular portion of the side wall of the body constituting said primary hinge extends radially inwardly of the body between the upper and lower side wall portions thereof, and the other relatively flexible portion of said side wall constituting said secondary hinge is disposed adjacent the junction of the upper side wall portion and the upper end wall of the body.

18. A hypodermic injection device according to any of claims 11 to 17 wherein the upper side wall portion tapers from a minimum thickness adjacent said primary hinge at one end thereof to a maximum thickness at the opposite end thereof.

19. A hypodermic injection device according to any of claims 14 to 17 wherein the primary hinge is at the lower end of the upper side wall portion and the upper side wall portion tapers from a minimum thickness at the primary hinge to a maximum thickness at the opposite end thereof.

20. A hypodermic injection device according to any of the preceding claims wherein the upper end wall is recessed at its inner surface and the recess is surrounded by an annular rim portion adapted to engage the closure member when the body is collapsed while permitting the inner portion of the closure member to be forced upwardly into the recess in the inner surface of said upper end wall.

21. A hypodermic injection device according to claim 20 wherein the inner portion of the closure member is a generally cylindrical portion having an axial height substantially greater than the thickness of the surrounding portions of the closure member.

22. A hypodermic injection device according to claim 20 wherein the inner portion of the closure member is a generally cylindrical portion having an axial height substantially greater than the thickness of the surrounding portions of the closure member and projecting above and below the adjacent surrounding portion of the closure member.

23. A hypodermic injection device according to claim 20 wherein the inner portion of the closure member is a generally cylindrical portion having an axial height substantially greater than the thickness of the surrounding portions of the closure member, the upper end of the generally cylindrical inner portion of the closure member being recessed to receive and guide the pointed end of the needle into the center thereof when the closure member is applied to the body to close the same.

24. A hypodermic injection device according to any one of the preceding claims wherein the cup-shaped hollow body includes a flange portion extending outwardly from its mouth, an annular groove located in said flange portion, an electrically conductive annular ring placed in said annular groove, the closure member extending contiguous with said flange portion, said annular ring being adapted for excitation by an electrical induction coil to electrically heat the material of the flange portion and the portion of the closure member contiguous to it.

25. A disk-like diaphragm for closing a cup-shaped collapsible body of a hypodermic injection device having a needle mounted axially therein for penetrating the diaphragm when the body is collapsed, said diaphragm having an annular outer portion, an inner portion, and a relatively flexible intermediate portion connecting said inner and outer portions to permit relative movement therebetween, said inner portion being relatively rigid and of substantial axial thickness with its lower end projecting axially below said flexible intermediate portion and having a passage extending axially into its upper end and terminating short of its lower end to leave a relatively thin wall closing the lower end of said passage.

26. A diaphragm according to claim 25 wherein the intermediate portion thereof is configured to form at least one annular corrugation surrounding said inner portion and permitting both axial and tilting movement thereof relative to said outer portion of the diaphragm.

27. A diaphragm according to claim 25 or 26 wherein the outer portion thereof is a flat annulus having a concentric annular rib integrally extending upwardly therefrom and spaced inwardly from the outer periphery thereof.

28. A generally cup-shaped collapsible body for a hypodermic injection device adapted to be closed by a closure member to contain a fluid to be injected, said body having a substantially circular upper end wall and a circumferentially extending side wall, said side wall having an upper side wall portion that is relatively flexible for progressively bending and rolling on itself from one end to the opposite end thereof and thereby turning inside-out to invert the upper part of said body within the confines of the lower part thereof, the lower portion of said side wall being of greater diameter and relatively more rigid and inflexible than said upper side wall portion, and said body also having a relatively flexible, circumferentially extending wall portion at said one end of said upper side wall portion for defining a primary hinge at which bending of said side wall will first occur in response to axial pressure on said body to initiate said

bending and rolling of said upper wall portion on itself.

29. A generally cup-shaped body according to claim 28 wherein the body is thinned adjacent the opposite end of said upper side wall portion to provide a secondary hinge for relieving elastic stresses created by progressively bending and rolling said upper side wall portion on itself.

30. A generally cup-shaped body according to claim 28 or 29 wherein the upper side wall portion tapers from a minimum thickness at said one end thereof to a maximum thickness at the opposite end thereof.

31. A hypodermic injection device substantially as hereinbefore described and illustrated in the accompanying drawings.

32. A disk-like diaphragm substantially as hereinbefore described and illustrated in the accompanying drawings.

33. A generally cup-shaped collapsible body substantially as hereinbefore described and illustrated in the accompanying drawings.

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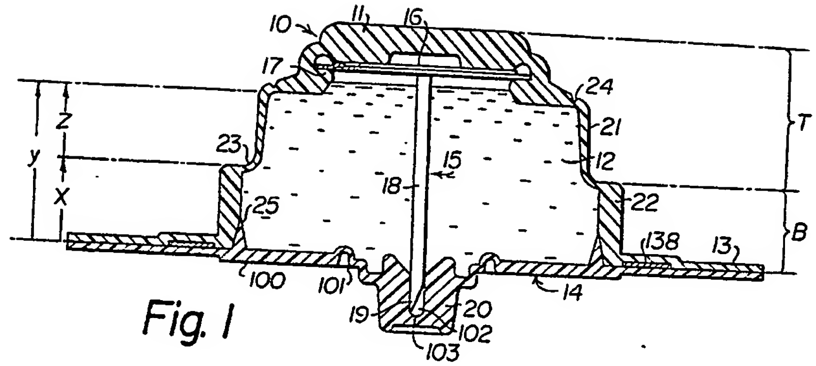

Fig. 1

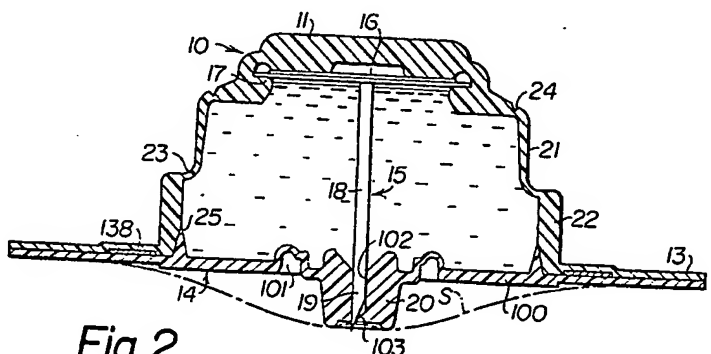

Fig. 2

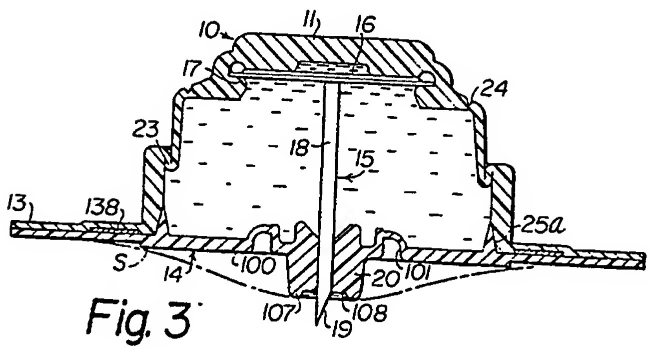

Fig. 3

1011301 COMPLETE SPECIFICATION

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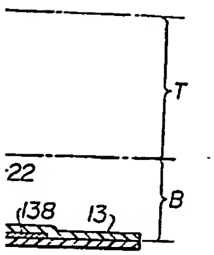

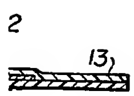

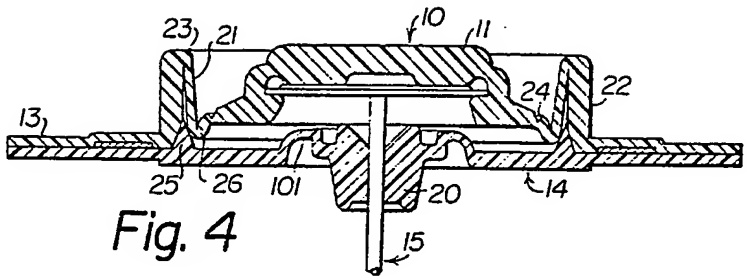

Fig. 4

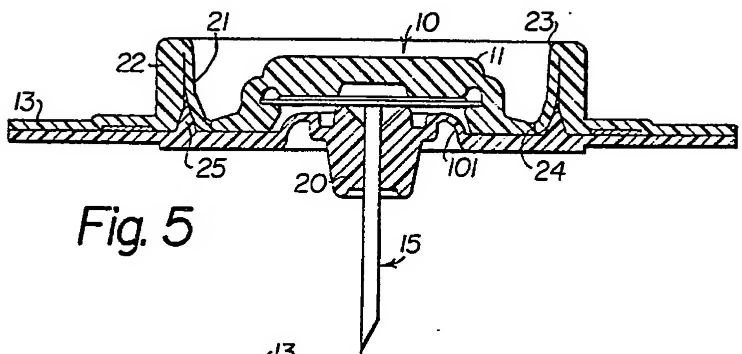

Fig. 5

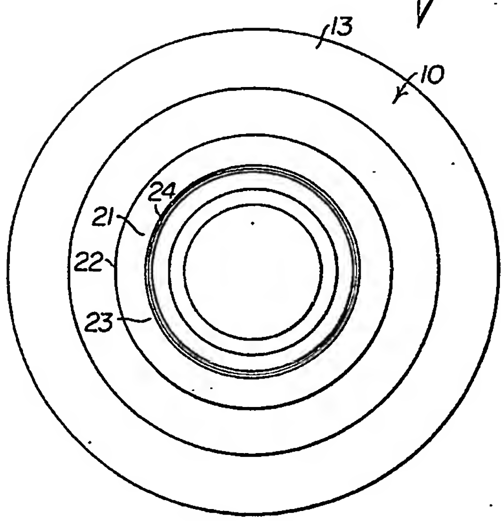

Fig. 6

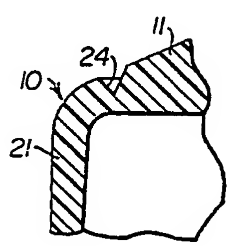

Fig. 7

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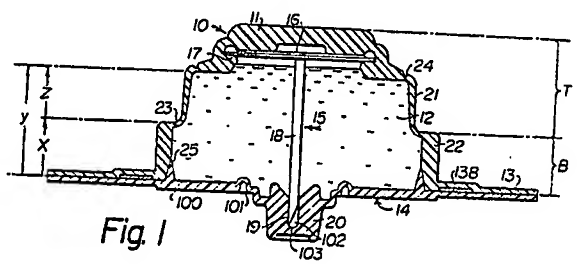


Fig. 1

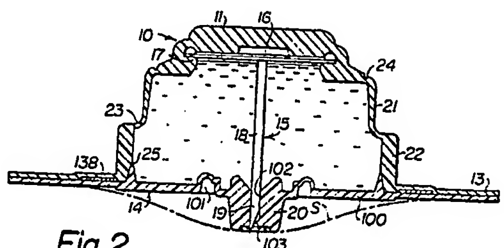


Fig. 2

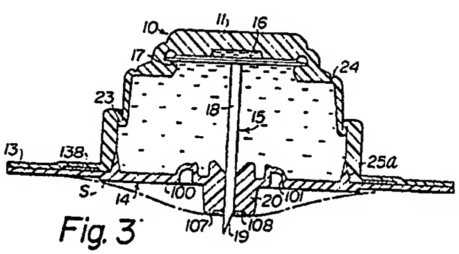


Fig. 3

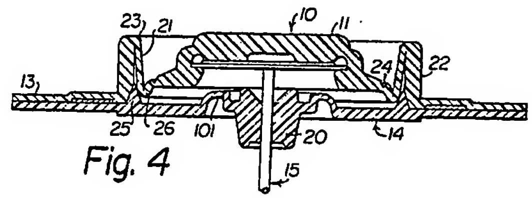


Fig. 4

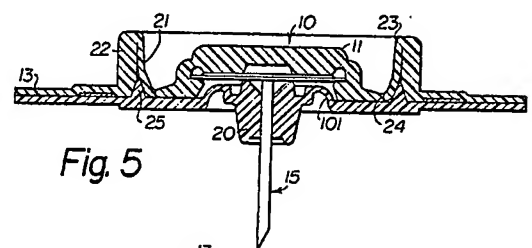


Fig. 5

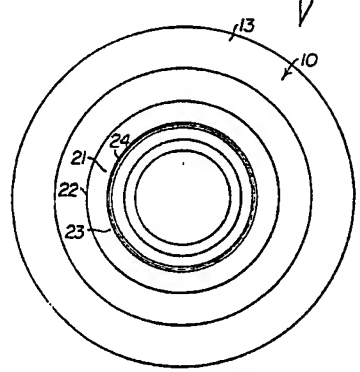
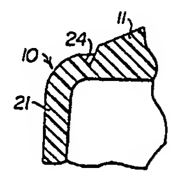


Fig. 6



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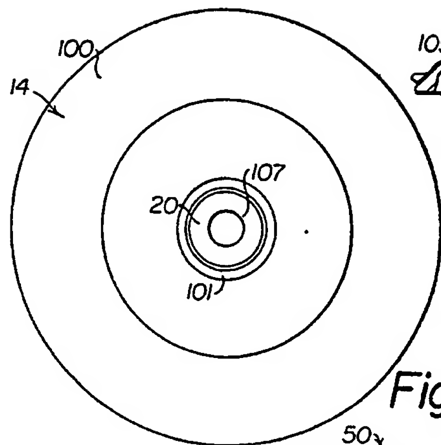

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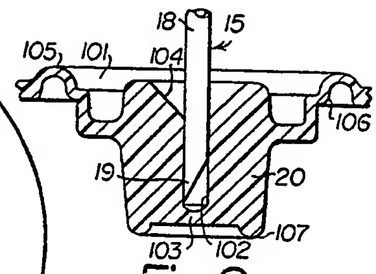
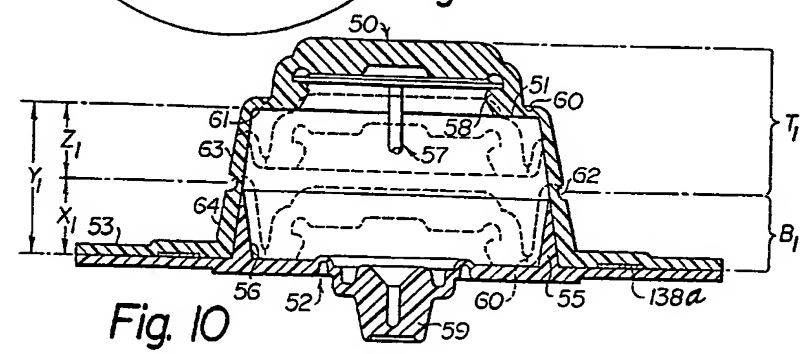


Fig. 9



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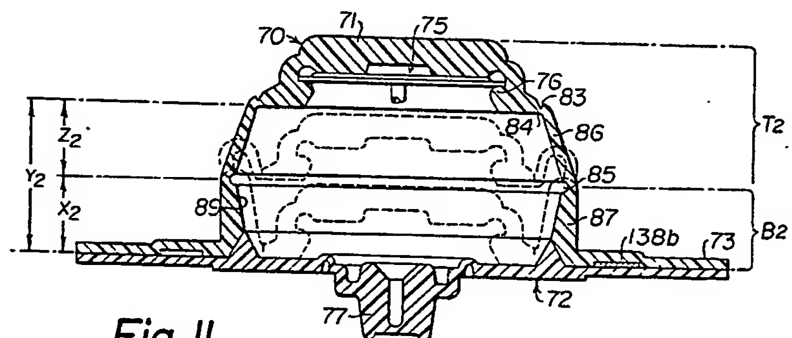


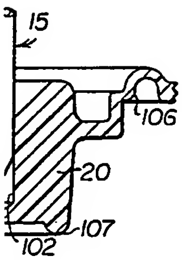
Fig. 11

1011301 COMPLETE SPECIFICATION

4 SHEETS

This drawing is a reproduction of the Original on a reduced scale

Sheets 3 & 4



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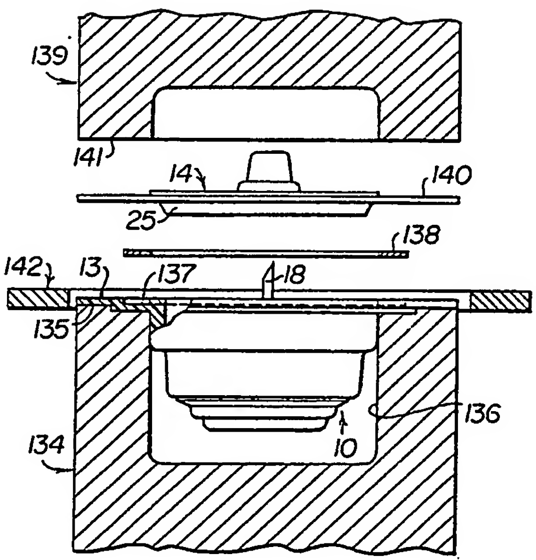
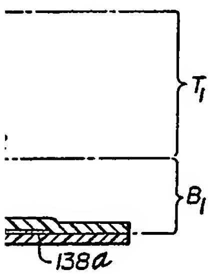


Fig. 12



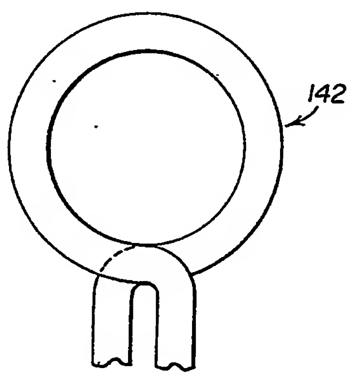
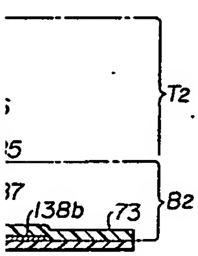


Fig. 13



1011301 COMPLETE SPECIFICATION

4 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

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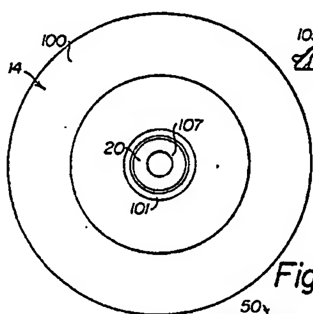

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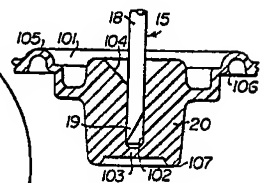

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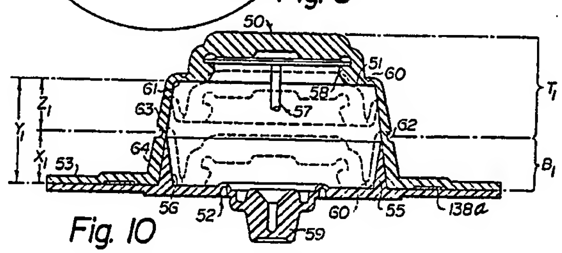

Fig. 10

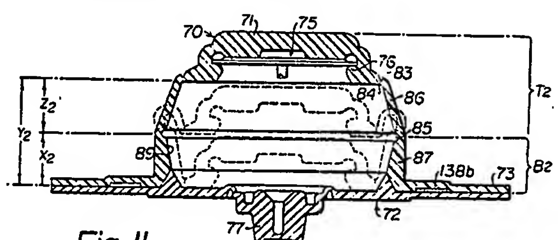

Fig. 11

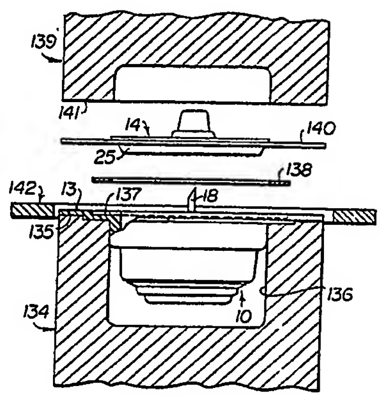

Fig. 12

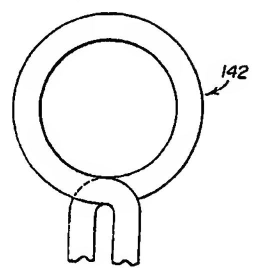

Fig. 13